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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/599,987 | 06/23/2000 | Richard E. Fulton | 3663-5 | 9195 |

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EXAMINER

WEBB, JAMISUE A

ART UNIT PAPER NUMBER

3761

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,987

Applicant(s)

FULTON, RICHARD E.

Examiner

Jamisque A. Webb

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16, 17 and 19-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 16, 17, 19, 31-40 and 43-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Claims 20-30, 41 and 42 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that The search and examination of the entire application can be made without serious burden to the examiner. This is not found persuasive because each set of claims in the restriction has a different combination of limitations that the other sets do not require, each group of claims has one item that is different from the other items, and therefore have to be given further consideration. The examiner considers this to be a serious burden to look for each set of limitations, and therefore the restriction requirement stands.

Applicant's have also argued that the method claims should be rejoined since the method corresponds with the pharmomechanical device, however, as stated in restriction requirement, the device can be used in a different method than what is claimed, see restriction requirement for details. Applicant has also argued that Groups I and II should be joined because they are linked as a means-plus-function, and that a means for providing a mechanical action to a vessel may include a motor attached to the catheter. There are many differences between Groups I and II that require the restriction between the two, Group II contains a "means for increasing surface area" and a "means for providing a mechanical action to a vessel", it states that the inventions can be shown to be unrelated if it can be shown that they have different modes of operation. The independent claim in Group II, does not specify what these means are, and therefore a "means for providing a mechanical action to a vessel" can also be a person's hand providing the movement instead of the motor used in Group I, and a "means for increasing the surface area of a clot" can be a corkscrew catheter instead of the catheter with a lumen in Group I.

Art Unit: 3761

The requirement is still deemed proper and is therefore made FINAL. Claims 1-14, 16, 17, 19, 31-40 and 43-55 are withdrawn from consideration.

Specification

2. The substitute specification filed 11/19/01 has not been entered because it does not conform to 37 CFR 1.125(b) because: it lacks a marked up copy of the specification including all changes made, must be submitted.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24-27, 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 24-27 recites the limitation "the mechanical means" or "said mechanical means". There is insufficient antecedent basis for this limitation in the claim.

6. With respect to Claim 27: the phrase "said device extends for a substantial length" is indefinite. It is unclear to the examiner, if this is a length of time, or if it is the length of the catheter? If it is a length of the catheter, the catheter is part of the device, so does that mean the device extends over itself? Due to the examiner not being able to determine the scope of this claim, a lack of prior art rejections does not indicate that this claim is allowable.

7. With respect to Claim 41: the phrase “intermittent motion of the catheter is provided by a pump that delivers a lytic agent” is unclear and indefinite. Does this mean that the delivering of the agent creates the motion of the catheter, if so then why would you need a “motor which regulates intermittent movement of said catheter”? Are their two “means for providing mechanical action to a vessel”? How can the means be both?
8. With respect to Claim 41, the phrase “programmable pulse” is unclear. It is unclear to the examiner how a pulse can be programmable. Does this mean that you program the pulse? Or do you program the pump to deliver the lytic agent in pulses?
9. With respect to Claim 42: the phrase “duration of said pulses are programmable” is indefinite. What is it programmable into, the pump or the motor?

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 20-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Cragg et al.

(6.063.069).

12. With respect to Claims 20 and 26: Cragg discloses the use of a pharmomechanical device, where a thrombolytic agent is pumped through a catheter (10) which is used to break up a

Art Unit: 3761

clot, and therefore increase the surface area of the clot (see abstract). The thrombolytic agent being delivered using a power injector, or a programmable pump (column 3, lines 18-22), thereby providing a "means for providing mechanical action". Cragg discloses the catheter infusion segment can be advanced back and forth by a physician (column 3, lines 55-58), therefore also providing mechanical action to the vessel. Cragg discloses the catheter having holes in a corkscrew fashion (see Figures 5-9). Cragg also discloses the catheter does not damage the veins (column 4, lines 1-8).

13. With respect to Claims 21-23: The power injector is programmable (column 6, lines 23-51), and therefore it is the examiner's position that the power injector is fully capable of delivering the thrombolytic agent for more than a 24 hour period of time.

14. With respect to Claim 24, 25, 29 and 30: Cragg discloses the power injector delivers 5 mL at a rate of 25 mL per second therefore taking 0.2 seconds to deliver the agent, and delivers at a rate of every 10 seconds, therefore the ratio of inactivity (10 seconds) to activity (0.2 seconds) of 50.

15. With respect to Claims 28: See column 6, lines 52-65.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3761

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al. (6,063,069) in view of Monetti et al. (6,030,397).

19. With respect to Claim 41: Cragg, as disclosed above for Claim 20, discloses all the claimed limitations, teaches that a physician moves the catheter around and fails to disclose programmable motor which regulates intermittent movement of the catheter. Monetti discloses the use of the catheter being controlled by an internal drive motor 50, where the motor rotates between 500-300 rpm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the catheter of Cragg, be modified to be controlled by the motor of Monetti, in order to control the catheter to be moved at constant speeds and directions that allow the blot clot to be broken up more effectively. (See Monetti Column 14)

20. With respect to Claim 42: See Cragg, column 6, lines 19-34.

Response to Amendment

21. Applicant's arguments with respect to the rejection mailed 7/18/01 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shiber (5,443,443), Kotula et al. (5,569,275) and Nita et al. (5,957,882) disclose catheter systems used to break up blood clots.

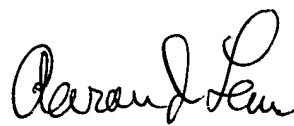
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamisue A. Webb whose telephone number is (703) 308-8579.

The examiner can normally be reached on M-F (7:30 - 4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703)308-2262. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jaw 
July 15, 2002


Aaron J. Lewis
Primary Examiner